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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,618	Applicant(s) MISHRA ET AL.	
	Examiner PABLO WHALEY	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010 and 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,41-55 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,41-55 and 83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Species A (corresponding to claim 47) in the reply filed on 09/13/2010 is acknowledged. However, after further consideration the species election is withdrawn due to lack of search burden. Accordingly, claims 47, 51, and 52 are hereby rejoined.

Preliminary Amendments

The preliminary amendment of the specification, filed 10/17/2005, has been fully considered. The preliminary amendment of the claims, filed 10/17/2005, has been fully considered.

Status of Claims

Claims 1, 41-55, and 83 are currently pending.

Claims 1, 41-55, and 83 are under consideration.

Claims 2-40 and 56-82 are cancelled.

Priority

The priority claim to provisional application 60/427903, filed 11/20/2002, is acknowledged.

Oath/Declaration

The oath filed 08/17/2007 is acceptable.

Information Disclosure Statement

The IDS statement filed 10/17/2005 has been entered and considered.

Specification

The specification is objected to because of the following including informalities:
There is no Brief Description of the Drawings as required by 37 CFR 1.74.

When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter). Correction is requested.

Drawings

The drawings filed 10/17/2005 are objected to as failing to comply with 37 CFR 1.84 because Figure 2 appears to be a duplicate of Figure 1. Figure 2 is not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

METHOD CLAIMS

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

According to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process under 35 U.S.C. 101 include: (i) No recitation of a machine or transformation (either expressed or inherent); (ii) Insufficient recitation of a machine or transformation (e.g. a general recitation of a machine that it covers any machine capable of performing the claimed method steps), or a recitation of the machine that is tangentially related to the performance of the steps or merely involves insignificant activity (e.g. data gathering); (iii) The claim is not directed to an application of a law of nature; and (iv) The claim is merely a statement of a general concept (e.g. abstract mathematical concepts or algorithms). It is noted that where the machine or transformation test (i.e. M-or-T test) is not met, analysis is extended to determine whether the claims read on an abstract idea. The prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to

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another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (See *In re Comiskey*, Fed. Cir., No. 2006-1286, 9/20/07; *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972).

With regards to claim 1, the claimed process for producing a genome wide map does not require a tie to a specific machine requires preparing chromosome maps, and producing a portion of the genome wide map based on chromosome maps. This process does not require a tie to a specific device, which weights against eligibility under 35 U.S.C. 101, part (i), as discussed above, since the claimed methods are not tied to a specific machine, and against eligibility under 35 U.S.C. 101, part (iv), because the claimed method steps are merely a statement of a general concept (e.g. abstract mathematical concepts or algorithms).

In the analysis of whether claim 1 transforms (either explicitly or inherently) any particular physical article, limitations directed to producing a portion of a genome map based on chromosome maps are noted. However, these limitations do not necessarily require the use of physical reagents or physical processes. Therefore the claimed methods do not transform (either explicitly or inherently) any particular physical article; e.g. by requiring that a particular physical assay is performed. Thus, the claimed method is wholly directed to an abstract idea, and therefore is directed to non-statutory subject matter under 35 U.S.C. 101.

SOFTWARE CLAIMS

Claims 41-55 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The instant claims are directed to a “software arrangement” comprising instructions which, when executed on a processing device, configures the device to produce a genome wide map. It is noted that the software arrangement could be capable of configuring a processing device to perform the instructions “when executed on a processing device”, however the claimed instructions are not explicitly required to be embodied on a computer. Therefore, the claims do not comprise any limitations such that the “software arrangement” is interpreted as a physical product or a method. Therefore the claimed computer readable media read on programs, per se, which are not statutory.

SYSTEM CLAIMS

Claim 83 is rejected under 35 U.S.C. 101 because this claim is drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The instant claim is drawn to a system comprising a storage medium including software that is executed to perform a process. However, the claimed system is not limited to comprise any hardware elements such that it is interpreted to be a physical article of manufacture. Furthermore, no description or limiting definition for the claimed “storage medium” is provided in the specification such that it would be interpreted as physical elements of the claimed system. Accordingly, the claimed system reads on a program, per se, because the claimed “storage medium” is not defined to be non-transitory hardware system components. Therefore the instant claims are not statutory.

Claim Rejections - 35 USC § 112, 2nd Paragraph

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 1, 41-55, and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 41 and 55 are also rejected due to said dependency.

Claims 1, 41, 55, and 83 (step b) recite producing "a portion of the at least one genome wide map", wherein the at least one genome wide map comprises...". Although the claims are directed to producing genome wide maps, as stated in the preamble, there is no previous step in the claims where a genome wide map has actually been produced. Therefore, there is lack of antecedent basis for "a portion of the at least one genome wide map." This rejection could be overcome, for example, by including a previous step for producing a genome wide map.

Claims 41 and 55 recites comprising "the processing arrangement" in steps (a) and (b). There is insufficient antecedent basis for this limitation in the claim. This rejection could be overcome, for example, by amending the claims to recite "processing device."

Claim 45 recites "The software arrangement according to claim 41, wherein the genome wide map comprises two maps per chromosome is assembled from the at least one single molecule map data set". The "wherein" clause and the use of passive language (i.e. is assembled) makes it unclear what positive limitation of the claimed software arrangement is intended. For example, is this a further limitation of the genome map, or an active process step (e.g. assembling a genome map using one single molecule map data set)? If the latter is intended, this rejection could be overcome by amending the claim to recite active language (i.e. assembling). Clarification is requested.

Claim 53 recites a software arrangement, wherein steps are performed within a particular time limit, and "the particular time is a sub-quadratic function." It is unclear what limitation of the claimed software arrangement is intended. The specification does not provide a limiting definition for a "sub-quadratic" function such that the technical scope of this limitation is well defined. This rejection could be overcome by amending the claims to recite, for example, a software arrangement wherein steps are performed using a sub-quadratic function to represent time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 41-47, 48, 55, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (Genome Res. 2001 11: 1584-1593), in view of Buetow et al. (Nature Genetics, 1994, Vol. 6, p.391-393).

CLAIM SUMMARY

Claim 1 is directed to a process for producing at least one genome wide map, comprising the steps of: (a) preparing chromosome maps associated with at least one chromosome; and (b) producing a portion of the at least one genome wide map based

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on the chromosome maps, wherein the at least one genome wide map comprises at least one of a haplotyped genome wide map or a genotyped genome wide map.

Claims 41 and 55 are directed to a software arrangement which, when executed on a processing device, configures the processing device to produce at least one genome wide map the software arrangement comprising: (a) a first set of instructions which are capable of configuring the processing arrangement to prepare chromosome maps associated with at least one chromosome; and (b) a first set of instructions which are capable of configuring the processing arrangement to produce a portion of the at least one genome wide map based on the chromosome maps, wherein the at least one genome wide map comprises at least one of a haplotyped genome wide map or a genotyped genome wide map.

Claim 83 is directed to a system comprising a storage medium and software that performs the steps recited in claim 1.

PRIOR ART

Lim teaches computer-based methods for assembling optical maps into larger maps to construct genome wide (non-haplotype) restriction maps of micro-organisms [Abstract].

Regarding claims 1, 41, 55, and 83, Lim teaches methods and software for constructing optical maps using DNA associated with chromosomes [p. 1585, Optical Maps, Fig. 1, Fig. 4, and p.1591, col. 2], which reads on preparing chromosome maps associated with at least one chromosome because DNA is a component of a chromosome. Lim produces a series (i.e. portions) of optical maps are produced and

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visualized as a chromosome [Fig. 1] used for the construction of whole genome maps from genomic DNA molecules [p.1584, col. 2, ¶2, and Fig. 2], which reads on producing portions of genome wide maps constructed from chromosomal maps. Lim teaches software tools for performing the above methods [see e.g. p.1585, col. 2, last ¶], which reads on "software arrangements".

Lim is silent to a system comprising a storage medium for executing software. However, Lim inherently teaches these limitations because Lim teaches the execution of software programs, as set forth above, which REQUIRES that software is executed using a computer with a memory (i.e. storage medium).

Regarding claims 1, 41, 44, 47, 55, 83, the optical maps are constructed using single DNA molecules [Abstract].

Regarding claim 42, Lim teaches a genome wide map with at least one restriction site [p.1585, col. 2, ¶2, and Fig. 2a].

Regarding claim 43, Lim does not specifically teach software for producing less than all subparts of the genome wide map as ordered or unordered contigs. However, Lim suggests this limitation by teaching software for assembling maps into complete contigs [p.1585, col. 1, ¶3]. Therefore Lim makes obvious the use of software for producing parts of a genome wide map as ordered or unordered contigs.

Regarding claim 45, Lim teaches software for the assembly of single DNA maps [p.1585, col. 1, ¶3], which reads on genome wide maps comprising two maps per chromosome assembled from single molecule map data.

Regarding claim 46, Liu teaches in silico generated maps with error rates less than 10% [p.1585, col. 2, ¶3, ¶4], which reads on a single molecule map data set having an error in distance of about 10% between sites.

Regarding claim 48, map assembly relies on the use of two different restriction site markers (Xho I and Nhe I) [p.1585, Optical Maps], which reads on restriction site markers that can be distinguished.

Lim does not teach a genome wide map comprising a haplotyped or genotyped genome wide map, as in claims 1, 41, 55, and 83.

Buetow teaches computational methods and software for producing genome wide maps using genotyped marker data [Abstract, p.391, col. 2, ¶2, and p.393, col. 2, Methodology]. The genome wide maps use chromosome specific data sets diagnosed for pairwise chromosomal data to show linkage between families [p.393, col. 2], which suggests the use of genome wide maps in gene association studies.

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to have modified the genome wide maps taught by Lim by including the use of genotyped markers, as taught by Buetow, with a reasonable expectation of success, since one of ordinary skill in the art would have been aware of methods for integrating a plurality of genotyped markers into genome wide maps, as suggested by Buetow, above. The motivation would have been to improve maps for disease-based linkage studies, as suggested by Buetow [p.393, col. 2].

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Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (Genome Res. 2001 11: 1584-1593), in view of Buetow et al. (Nature Genetics, 1994, Vol. 6, p.391-393), as applied to claims 1, 41-47, 48, 55, and 83, above, and further in view of Cooke et al. (Mammalian Genome, 1996, 7, 157-159).

Lim and Buetow make obvious methods and software for producing genome wide maps, as set forth above.

Lim and Buetow do not teach site-based and interval-based polymorphisms detected in the genome wide map, as in claims 51 and 52.

Cooke teaches methods for programs for producing genome wide maps that include the use of a plurality of different polymorphic markers with various types of positioning [p.157, col. 1, ¶1, ¶2, and col. 2, ¶2] in order to create a map of markers for identifying disease related genes [p.157, col. 1, p.158, col. 2]. In at least one case, the maps use polymorphic markers of different intervals [p.157, col. 2, ¶1 and Fig. 1a], which reads on site and interval-based polymorphisms.

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to have used the genome wide maps made obvious by Lim and Buetow, for detecting site based or interval based polymorphisms, as taught by Cooke, with a reasonable expectation of success, since one of ordinary skill in the art would have been able to integrate polymorphic markers into genetic maps with predictable results, as suggested by Cooke [p.157, col. 1]. The motivation would have been to

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improve genetic analysis using improved and integrated genetic maps, as suggested by Cooke [p.158].

Claims 49, 50, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (Genome Res. 2001 11: 1584-1593), in view of Buetow et al. (Nature Genetics, 1994, Vol. 6, p.391-393), and in view of Cooke et al. (Mammalian Genome, 1996, 7, 157-159), as applied to claims 1, 41-47, 48, 51, 52, 55, and 83, above, and further in view of Anantharaman et al. (Genomics via Optical Mapping II: Order Restriction Maps, December 1996, pages 1-41), and in view of Kaltofen et al. (Mathematics Of Computation, 1998, Volume 67, Number 223, Pages 1179-1197).

Lim, Buetow, and Cooke make obvious methods and software for producing genome wide maps, as set forth above.

Lim, Buetow, and Cooke do not teach determining a conditional probability density expression based on errors, as in claims 49 and 50.

Lim, Buetow, and Cooke do not teach performing the preparation of genome wide maps within a particular time limit that is sub-quadratic function of a number of sites associated with input data, as in claim 53.

Lim, Buetow, and Cooke do not teach performing a disease gene association study based on at least one genome wide map, as in claim 54.

Anantharaman teaches computational methods and software for constructing optical maps based on single DNA molecules [see e.g. Section 1, pages 1 and 2]. In at

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least one case, this process includes the calculation of conditional probabilities based on errors in DNA size [e.g. see pages 4, ¶1, and page 14, Section 4.1]. Anantharaman also teaches procedures for optimization of the map alignment sites (i.e. number of restriction sites) by checking in polynomial time [page 5, ¶1, ¶2], which suggests the representation of time as sub-quadratic functions of a number of sites associated with input data because solving polynomials requires the use of quadratic functions.

Kaltofen teaches algorithms for sub-quadratic time factoring of polynomials that provide improved speed [Abstract].

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to have modified the method and software for producing genome wide maps made obvious by Lim and Buetow, by creating maps based on conditional probability density expressions, as taught by Anantharaman, above, with a reasonable expectation of success, since one of ordinary skill in the art would have recognized that probability distributions are commonly applied to optical image maps, as shown by Anantharaman [Section 4.1], and since Lim suggests the use of conditional probability algorithms [p.1592, col. 1, last ¶]. The motivation would have been to improve genome wide maps by accounting for sizing errors in the data, as suggested by Anantharaman [page 4, ¶3].

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to have modified the method and software for producing genome wide maps made obvious by Lim and Buetow, by preparing genome wide maps within a time limit that is sub-quadratic function of a number of sites associated with input data, with a

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reasonable expectation of success, since one of ordinary skill in the art would have recognized probabilistic software for sub-quadratic time factoring of polynomials, as taught by Kaltofen, and would have recognized the applications of this software for mapping alignment site data as a function of polynomial time [Anantharaman, page 5, ¶1, ¶2], which suggests the representation of time as sub-quadratic functions of a number of sites associated with input data since solving polynomials requires the use of quadratic functions. The motivation would have been to employ fast probabilistic algorithms for optimizing map alignment sites, as suggested by Anantharaman [page 5, ¶1, ¶2], and Kaltofen [Abstract].

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to have modified the method and software for producing genome wide maps made obvious by Lim and Buetow, by performing a disease gene association study based on at least one genome wide map, with a reasonable expectation of success, since Buetow suggests the use of genome wide maps in gene association studies [p.393, col. 2], and since one of ordinary skill in the art would have recognized that genome wide maps are commonly used for association studies, as suggested by Cooke [p.157, col. 1, ¶1]. The motivation would have been to improve genetic analysis of disease mapping, as suggested by Cooke [p.158. col. 1].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 11am-7pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631